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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 24 2005

Food and Drug Administration
Rockville MD 20857

David L. Rosen
Foley & Lardner LLP
3000 K Street, NW
Suite 500
Washington, DC 20007

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Re: Docket No. 2004P-0563/CP1

Dear Mr. Rosen:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated December 23, 2004, on behalf of Andrx Pharmaceuticals, Inc. Your petition requests that the Agency:

(1) Seek public comment, including formal written input from the Federal Trade Commission and the Department of Justice, on the potential short- and long-term effects of the marketing of "authorized generics" on consumers, generic drug producers, and competition; and

(2) Inform McNeil Specialty Pharmaceuticals that any authorized version of Concerta (methylphenidate hydrochloride) that is introduced and marketed as a generic drug before or during the initial product launch of the first approved abbreviated new drug application for methylphenidate hydrochloride will be regarded as misbranded and subject to regulatory action.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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